

REMARKS

Claims 1-2 and 4-13 are pending in the application.

The Examiner's claim rejection is overcome as set forth below.

I. TRAVERSE OF THE OBIOUSNESS REJECTION OF CLAIMS 1-2 AND 4-12

Claims 1-2 and 4-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al., in view of Copeland et al. and further in view of the McManus et al. article and Stokes et al. (USP No. 5,318,795).

It is the Examiner's position that McCormick et al. teaches most aspects of the claimed invention except for the mixing of reagents on a slide and using unstable staining solutions. The Examiner looks to the Copeland et al. reference for teaching the steps of applying a staining solution to a slide and mixing the solution on the surface of the slide by applying a gas stream or two gas streams so as to form a vortex. The Examiner further takes the position that McManus et al. discloses unstable staining solutions and that it would have been obvious to combine McManus et al. with Copeland et al. because Copeland et al. discusses applying multiple "reagents" to a biological sample. Moreover, it is the Examiner's opinion that Stokes et al. teaches the application of multiple reagents as part of a single staining step.

The Examiner's obviousness rejection is traversed as set forth below.

A. The Prior Art Does Not Disclose Or Suggest That Ingredients Comprising A Useful Staining Solution Can Be Individually Applied To A Biological Sample

The applicant's position in favor of claim patentability is quite simple – the prior art of record discloses applying staining solutions to biological samples. The staining solutions applied to the biological samples in the prior art are all premixed before they are applied to a biological sample. That is, the staining solutions are immediately useful for staining the biological samples and do not require the addition of further ingredients or mixing in order to make them functional. The prior art does not disclose or suggest the applicants invention - that ingredients that form a staining solution can be individually applied to a biological sample and mixed while in contact with

the biological sample to form a useful staining solution.

None of the prior art references cited by the Examiner disclose or suggest adding individual ingredients of solutions – staining solutions or otherwise – to a biological sample during any type of biological treatment procedures including staining procedures and thereafter forming, by mixing a useful reagent or staining solution. The Examiner has cited Stokes et al. for suggesting this teaching. However, the Examiner’s reliance on Stokes et al. is misplaced. Specifically, the Examiner has cited column 10, lines 34-38 of Stokes et al. which states:

“Where the claims are directed to a step in the staining process, it is understood that the step may comprise a single step where a combination of reagents are applied or sequential steps where more than one reagent or combinations of reagents is applied.”

The Examiner has concluded, incorrectly, that this excerpt of Stokes et al. teaches that “multiple reagents may be applied as part of a single staining step” (See page 5 of the November 18, 2003 Official Action). A complete reading of Stokes et al. shows that this cited excerpt does support the examiner’s obviousness rejection. Moreover, even if the examiner’s reliance on Stokes et al. is proper, the examiner has still failed to make out a *prima facie* case of obviousness.

Stokes et al. is directed to a method for replacing a procedure whereby biological samples on slides undergoing staining are sequentially dipped into solutions during the staining procedure with a process whereby the solutions are sequentially sprayed onto slides. Examples I and II and the specification of Stokes et al. all teach spraying solutions, including pre-mixed staining solutions, to biological samples located on slides. (See Examples 1 & 2 of Stokes et al.). Nowhere in Stokes et al. is there a disclosure or suggestion that individual staining solution ingredients can be independently applied to the biological samples by spraying. Instead, upon reading Stokes et al. in its entirety, it becomes clear that what is taught by the excerpt quoted and relied upon by the examiner is that, for purposes of the claims – the multiple steps of for example, the staining procedure identified, for example in Example 1, may together be considered a “step” for purposes of the claims. The excerpt cited by the examiner cannot be considered to mean – as the examiner suggests that multiple reagents may be applied as part of a single staining step to form a staining solution because there is absolutely no disclosure in Stokes et al. that would support this

interpretation of the cited statement.

Moreover, as discussed below, Stokes et al. cannot be fairly read to disclose that a “reagent” is anything other than a combination of ingredients that are immediately useful when applied to a biological sample. Therefore any reagent referred to in Stokes et al. are premixed and ready to use solutions.

B. The Obviousness Rejection Is Based Upon An Improper Hindsight Analysis Of The Prior Art

The Examiner’s obviousness rejection remains based upon an improper hindsight analysis of the prior art with the applicants’ invention in mind. For this reason, the Examiner should withdraw the obviousness rejection of all claims.

There is no teaching or suggestion in the prior art cited the Examiner that ingredients of an unstable staining solution my be applied independently and before mixing to a biological sample and thereafter allowed to form an unstable staining solution in contact with the biological material. Moreover, there is no disclosure or suggestion in the prior art that the term “reagent” as used in the prior art encompasses individual ingredients that together form a useful solution. Instead, the term “reagent” is used in the prior art to refer to solutions, that are useful alone – and without the addition of further ingredients – to perform a procedure or a procedure step.

What the Examiner has done is to evaluate the prior art in hindsight. In rejecting all claims for obviousness, the Examiner has clearly first considered the Applicants’ invention and then has viewed the prior art references in hindsight – with the Applicant’s invention in mind. This is not the correct obviousness analysis. “Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.” *See, e.g. , W.L. Gore & Assoc., Inc. v. Garlock, Inc. ,* 721 F.2d 1540, 1553, 220 UPSQ 303, 313 (Fed. Cir. 1983). Adherence to this methodology is important where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.” *Id.*

The prior art does not support the examiner’s interpretation that the term “reagent” to

include ingredients of a useful solution. Nowhere does the prior art use the term reagent in this context. The examiner's citation of an excerpt from a disclosure on a "periodic acid Schiff reaction" can not alter this conclusion because the Examiner has sought out this definition, in hindsight, in order to force the prior art to be interpreted in a manner that is contrary to the teaching of each of the references. When considered for their teachings alone, one of ordinary skill in the art would not understand the references cited by the examiner to teach or suggest the claimed invention. Instead, one of ordinary skill in the art would understand that the references, when combined, disclose that the pre-mixed unstable staining solutions of McManus or the pre-mixed staining solutions of Stokes et al. (and not individual staining solution ingredients) can be applied to samples using the methods and apparatuses of Stokes et al., McCormick et al. and Copeland et al. Clearly, the examiner has improperly considered the prior art references in hindsight. As a result, the obviousness rejection of all application claims should be withdrawn.

Conclusion

For the reasons indicated above, claims 1–2 and 4–13 are believed to be patentable over the prior art of record. Favorable reconsideration and allowance of the pending application is, therefore, courteously solicited.

Respectfully submitted,

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